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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,246	09/12/2006	Mark L. Lawrence	028186.61646	5820

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BUTLER, SNOW, O'MARA, STEVENS & CANNADA PLLC
6075 POPLAR AVENUE
SUITE 500
MEMPHIS, TN 38119

EXAMINER	
NAVARRO, ALBERT MARK	

ART UNIT	PAPER NUMBER
1645	

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08/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,246	LAWRENCE ET AL.	
	Examiner	Art Unit	
	Mark Navarro	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) *6,7,13-17,20,26-34 and 46-85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-12,18,19,21-25 and 35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment filed May 20, 2009 has been received and entered. Claim 1-85 remain pending in the instant application, of which claims 6-7, 13-17, 20, 26-34, and 46-85 have been withdrawn from further consideration as drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claims 38 and 43 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "or other appropriate promoter" is withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section

> 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The rejection of claims 1-5, 9-12, 21-25, 35-38 and 41-43 under 35 U.S.C. 102(b) as being anticipated by Anderson et al in light of Heithoff et al is maintained.

Applicants are asserting that Heithoff et has not been used to show that Anderson contains an enabling disclosure, or to explain the meaning of any term in the primary reference, or to show a characteristic disclosed in Anderson is inherent. Applicants further assert that as a result of the election of species, every claim has been directed toward Pasteurella multocida. Applicants finally assert that a Declaration by Mark Lawrence shows that the presence of the dam gene in Pasteurella multocida was first discovered by our inventors in 1999.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that Heithoff et has not been used to show that Anderson contains an enabling disclosure, or to explain the meaning of any term in the primary reference, or to show a characteristic disclosed in Anderson is inherent. However, Applicants are again directed to the disclosure of Anderson et al, which sets forth of an E. coli strain which contains a DNA adenine methylase (Dam) mutation. (Example 1). This teaches the limitations of claim 1 "strain of bacteria comprising altered DNA adenine methylase (Dam) activity." Anderson et al did not classify the mutation as "attenuated." However, Heithoff et al teach that bacteria lacking DNA adenine

methylase "showed severe defects in colonization of deeper tissue sites (e.g., attenuated). Accordingly, Heithoff et al do nothing more than show that DNA adenine methylase mutations are indeed “attenuated” (e.g., characteristic which is inherent).

Second, Applicants further assert that as a result of the election of species, every claim has been directed toward Pasteurella multocida. Applicants appear to be under a mistaken impression as to what an election of species entails. Applicants assertion that “every claim has been directed toward Pasteurella multocida is simply incorrect. An election of species is only applied to claims which positively recite multiple species or a species distinct from the elected species, Applicants choose the first species for examination, if nothing is found, the Examiner then moves to a second species of his/her choosing. However, Applicants need to look at the rejected claims, not a single one of them recites individual species, rather generic claims directed to "strain of bacteria." An election of species has absolute zero effect on these broad generic claims. Accordingly, Applicants arguments are simply incorrect.

Applicants finally assert that a Declaration by Mark Lawrence shows that the presence of the dam gene in Pasteurella multocida was first discovered by our inventors in 1999. However, while Exhibit A and Exhibit B of the Declaration, presumably by Mark Lawrence was included, no Declaration by Mark Lawrence was enclosed. However, even if such a Declaration were to set forth what Applicants assert, it would be insufficient to overcome the outstanding rejection for the reasons set forth above, the rejected claims are simply not limited to Pasteurella multocida as Applicants appear to erroneously believe.

The claims are directed to an attenuated strain of a bacteria, said bacteria comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.

Anderson et al (US Patent Number 4,798,791) disclose of E. coli strain GX3003 that contains a DNA adenine methylase (Dam) mutation. (See Example 1).

Heithoff et al (Science Vol. 284, pp 967-970, May 1999; IDS REF "BY") disclose that bacteria lacking DNA adenine methylase were fully proficient in colonization of mucosal sites but showed severe defects in colonization of deeper tissue sites. Heithoff et al report that Dam inhibitors are likely to have broad antimicrobial action, and Dam negative derivatives of these pathogens may serve as live attenuated vaccines. (See abstract).

Accordingly, the Dam mutation disclosed by Anderson et al is deemed to be an attenuating mutation.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-5, 8-12, 18-19, 21-25, and 35-45 under 35 U.S.C. 102(a & e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mahan et al is maintained.

Applicants are asserting that as submitted in the Declaration by Mark Lawrence, the presence of the dam gene was not even known in P. multocida prior to the

discovery by the applicant. Applicants further assert that because the existence of the dam gene in Pasteurellacea was unknown prior to the discovery by the inventor, the invention cannot be obvious, and it is apparent that Mahan was broadly claiming an invention of which he was not in possession of at the time of his application.

Applicants arguments have been fully considered but are not found to be persuasive.

First, Applicants assert that as submitted in the Declaration by Mark Lawrence, the presence of the dam gene was not even known in P. multocida prior to the discovery by the applicant. However, as set forth above, the actual Declaration by Mark Lawrence was not included. To the extent that the Declaration would say what Applicants assert, it would still be insufficient to overcome the rejection of record. Applicants specification (page 4) states that "dam genes have been identified in Pasteurellaceae as a result of genome sequence projects" and specifically cites May et al (PNAS Vol. 98, pp 3460-3465, 2001). This is a full two years prior to Applicants earliest claim of priority, accordingly, the Dam genes were publicly available.

Finally, Applicants assert that it is apparent that Mahan was broadly claiming an invention of which he was not in possession of at the time of his application. However, Applicants are respectfully directed to the Examples of Mahan. Examples 1-5 show attenuated Salmonella having Dam mutations, Example 6 shows attenuated Vibrio having Dam mutations, and Example 8 shows attenuated Yersinia having Dam mutations. Mahan has enabled a genus of a bacterial claim by reducing to practice multiple species. This combined with the express teaching of applicability of Dam

mutations in P. multocida (paragraphs 88, 91, 154 and claims 11-12) is not a lack of possession of the genus as Applicants assert. In comparision, Applicants instant specification shows a reduction to practice of fewer species having Dam mutations than Mahan, yet Applicants have claimed a broad genus of Dam mutated "strain of bacteria" based on their smaller number of species? Applicants arguments could easily be construed to indicate that their own claims do not meet the written description guidelines for the broad genus of bacteria. In any event, the asserted lack of written description for the claims of US Publication 2002/0068068 is not found to be persuasive.

The claims are directed to an attenuated strain of a bacteria, said bacteria comprising altered DNA adenine methylase (Dam) activity such that the bacteria are attenuated.

Mahan et al (US Publication 2002/0068068) disclose of compositions containing pathogenic bacteria having non-reverting genetic mutations which alter activity of DNA adenine methylase (Dam) resulting in attenuation and methods of using these compositions to elicit an immune response to produce antibodies. (See abstract and claims). Mahan et al specifically set forth that the starting bacteria, to which a mutation of DNA adenine methylase was done, included Paseurella multocida. (See detailed paragraph 88; and claims 11-12).

For reasons of record as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Navarro/
Primary Examiner, Art Unit 1645
August 17, 2009